

SEP 28 2007

Application No. 10/762,439
Amendment dated September 28, 2007
Reply to Office Action of May 30, 2007

Docket No.: CDSI-P01-041

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A sustained release drug device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising an adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
- (ii) a first coating on the surface of the drug core, that is substantially impermeable to the passage of the adrenergic agent, having one or more openings therein which permit diffusion of the adrenergic agent, and which is substantially insoluble and inert in body fluids and compatible with body tissues; and
- (iii) one or more additional coatings that are permeable to the passage of the adrenergic agent, and which are substantially insoluble and inert in body fluids and compatible with body tissues;

wherein the first and additional coatings are disposed about the inner drug core so as to produce, when implanted, a substantially constant rate of release of the adrenergic agent from the device.

2. (Currently Amended) A sustained release drug device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising an adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
- (ii) a first coating on the surface of the drug core, that is substantially impermeable to the passage of the adrenergic agent, having one or more openings therein which permit diffusion of the adrenergic agent, and which is substantially insoluble and inert in body fluids and compatible with body tissues; and
- (iii) one or more additional coatings that are permeable to the passage of the adrenergic agent, and which are substantially insoluble and inert in body fluids and compatible with body tissues;

Application No. 10/762,439
Amendment dated September 28, 2007
Reply to Office Action of May 30, 2007

Docket No.: CDSI-P01-041

wherein the impermeable coating has sufficient dimensional stability to be filled with an adrenergic agent core without changing its shape.

3. (Original) The device of claim 1, wherein the impermeable coating has sufficient dimensional stability to be filled with an adrenergic agent core without changing its shape.

4. (Withdrawn) A method for administering an adrenergic agent to the ciliary body of an eye, the method comprising implanting a sustained-release device in or adjacent to the eye, whereby the device delivers the adrenergic agent to the ciliary body of the eye, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 30 days.

5. (Withdrawn) A method for administering an adrenergic agent to the ciliary body of an eye, the method comprising implanting a sustained-release device according to any one of claims 1 - 3 or claim 14 in or adjacent to the eye, whereby the device delivers the adrenergic agent to the ciliary body of the eye, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 30 days.

6. (Withdrawn) The method of claim 4, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 180 days.

7. (Withdrawn) The method of claim 5, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 180 days.

Application No. 10/762,439
Amendment dated September 28, 2007
Reply to Office Action of May 30, 2007

Docket No.: CDSI-P01-041

8. (Withdrawn) The method of claim 4, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 360 days.

9. (Withdrawn) The method of claim 5, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 360 days.

10. (Currently Amended) The device according to any one of claims 1-4, 6, and 8, wherein the adrenergic agent is selected from the group consisting of brimonidine, aapraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunolol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.

11. (Withdrawn, Currently Amended) The method according to claim 5, wherein the adrenergic agent is selected from the group consisting of brimonidine, aapraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunolol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.

12. (Withdrawn, Currently Amended) The method according to claim 7, wherein the adrenergic agent is selected from the group consisting of brimonidine, aapraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunolol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.

13. (Withdrawn, Currently Amended) The method according to claim 9, wherein the adrenergic agent is selected from the group consisting of brimonidine, aapraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunolol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.

Application No. 10/762,439
Amendment dated September 28, 2007
Reply to Office Action of May 30, 2007

Docket No.: CDSI-P01-041

14. (Currently Amended) A sustained release drug delivery device adapted for insertion in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising at least one adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
- (ii) a coating layer on the surface of the drug core that is substantially impermeable to the passage of the at least one adrenergic agent, having one or more openings therein which permit diffusion of the adrenergic agent(s), and that is substantially insoluble and inert in body fluids and compatible with body tissues; and

wherein the coating is disposed about the inner drug core so as to produce, when inserted a substantially constant rate of release of the adrenergic agent(s) from the device.

15. (Cancelled)

16. (Original) The sustained release drug delivery device of claim [[15]]14, wherein the polymer matrix is bioerodible.

17. (Original) The sustained release drug delivery device of claim 14, wherein the device is formed by co-extruding the inner drug core and the coating layer.

18. (Currently Amended) A sustained release drug delivery device adapted for insertion in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising at least one adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
- (ii) a coating layer on the surface of the drug core that is partially or substantially permeable to the passage of the at least one adrenergic agent, having one or more openings therein which aid diffusion of the at least one adrenergic agent, and that is substantially insoluble and inert in body fluids and compatible with body tissues; and

Application No. 10/762,439
Amendment dated September 28, 2007
Reply to Office Action of May 30, 2007

Docket No.: CDSI-P01-041

wherein the coating is disposed about the inner drug core so as to produce, when inserted, a substantially constant rate of release of the at least one adrenergic agent from the device.

19. (Cancelled)

20. (Original) The sustained release drug delivery device of claim ~~[[19]]~~18, wherein the polymer matrix is bioerodible.

21. (Original) The sustained release drug delivery device of claim 20, wherein the device is formed by co-extruding the inner drug core and the coating layer.